

FORM PTO-1390  
(REV. 1-98)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

0020-4802P

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

**09/743750**

INTERNATIONAL APPLICATION NO.

PCT/JP99/03837

INTERNATIONAL FILING DATE

16 JULY 1999

PRIORITY DATE CLAIMED

16 JULY 1998

**TITLE OF INVENTION**

FORMULATIONS USEFUL FOR IMMUNOTHERAPY FOR CANCERS CONTAINING BACTERIAL COMPONENT AS AN  
ACTIVE INGREDIENT

**APPLICANT(S) FOR DO/EO/US**

AZUMA, Ichiro; HAMAMATSU, Norio; FUJINAGA, Toshio

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19<sup>th</sup> month from the earliest claimed priority date
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☒ has been transmitted by the International Bureau. WO00/03724
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(3)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(2)).
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98./International Search Report
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.  
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:  
FORM PCT/IPEA/409 - INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
ENGLISH TRANSLATION OF ARTICLE 34 CLAIMS  
EIGHT (8) SHEETS OF FORMAL DRAWINGS

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**Amendment under Article 11 of the Law Concerning  
International Application under PCT**

**1. International Application Number**

PCT/JP99/03837

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**4. Date of Notification**

22.02.00

**5. Object to be amended**

Claims

**6. Content of amendment**

As shown in the attached sheet, a stabilizer is restricted to an amino acid or urea in independent claims of claims 1 and 6, whereas a bacterial component is restricted to a BCG-CWS and *Nocardia rubra* CWS, and step (b) is amended in an independent claim of claim 11. In claims 5 and 10, a stabilizer is amended to an amino acid. Claims 4, 9, and 12 are deleted, and, in the dependent claims from these claims, claim numbers showing these claims are amended. Claims 21 to 25 are added.

**7. Appendix**

Amended page 45, 46, 47, 48-1 and 48-2 of the claims are herein attached.